

Subsequent HIV Infection Among Men Who Have Sex with Men Who Used Non-Occupational Post-Exposure Prophylaxis at a Boston Community Health Center: 1997–2013

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Abstract

Non-occupational post-exposure prophylaxis (NPEP) has been recommended to prevent HIV acquisition for nearly 20 years. However, limited behavioral and clinical outcome data exist after men who have sex with men (MSM) present for NPEP. We reviewed the electronic medical records of HIV-uninfected adults who presented for NPEP at a large community health center in Boston between July, 1997 and August, 2013. Data from 894 patients were analyzed, 88.1% of whom were MSM. Consensual unprotected sex was the most common reason for NPEP visits among MSM (64.2%), followed by condom failure (30.6%). The HIV serostatus of the partner was unknown for 64.4% of the MSM, positive with unknown treatment status for 18.1%, positive and not on treatment for 4.1%, and positive and on treatment for 13.4%. Thirty-nine patients subsequently became HIV-infected (4.4%), all of whom were MSM. The MSM-specific HIV incidence after NPEP use was 2.2 cases per 100 person-years. Incident HIV infection was associated with younger age (AHR=0.94; $p=0.003$), being Latino (AHR=2.44; $p=0.044$), and/or being African American (AHR=3.43; $p=0.046$). Repeated NPEP use was not associated with incident HIV infection (AHR=0.67; $p=0.26$). Younger MSM of color who access NPEP, in particular, may benefit from early HIV risk-reduction and pre-exposure prophylaxis counseling.

Introduction

APPROXIMATELY 50,000 NEW HIV INFECTIONS occur in the United States each year,¹ among which the greatest burden of transmissions occur among men who have sex with men (MSM),² highlighting the need for additional prevention approaches in this population. HIV non-occupational post-exposure prophylaxis (NPEP) is an effective form of biomedical prevention that was first recommended by the CDC in 2005 for sexual, injection drug use, and other exposures outside of a work environment.³ NPEP use has not been associated with increased high-risk behavior in some reports, suggesting that the experience might create an “educable moment” for risk reduction counseling.^{4,5} Recent studies have reported improved tolerability with newer NPEP regi-

mens among MSM who presented for NPEP.^{6,7} However, several studies found that NPEP awareness in at-risk MSM was low, ranging from 28% to 47.5%,⁸⁻¹⁰ and a British study observed that awareness of NPEP among MSM in an HIV-infected cohort in 2011 was 65.8% and significantly higher among younger individuals and those diagnosed after 2006.¹¹ A recent US study documented underutilization of NPEP in two urban settings.¹² In addition to reducing the risk associated with a given exposure, the NPEP encounter may provide clinicians the opportunity to identify patients with ongoing risk and refer them for PrEP as per the 2014 US Public Health Service PrEP clinical practice guideline.¹³ In order to identify those NPEP users at highest risk for HIV acquisition and to guide the transition from NPEP to PrEP, we examined the risk factors associated with HIV acquisition

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among MSM who presented for NPEP at a Boston community health center, the largest NPEP provider in New England, since the inception of its program in 1997.

Methods

Patients and procedures

This study is a retrospective review of NPEP users at a large urban community health center in Boston, MA, who presented between July 1, 1997 and August 1, 2013. Any patient who had a prescription for antiretroviral medication in their electronic medical record during this time period without a diagnosis of HIV was screened for study eligibility. Inclusion criteria included: (1) age 18 years or older at the time of first NPEP visit; (2) documentation of sexual or non-occupational intravenous drug needle possible exposure to HIV; and (3) negative baseline HIV test at the time of NPEP visit. Patients were excluded if they had: confirmatory positive HIV testing within 30 days of being on antiretrovirals (i.e., an immediate NPEP failure), received a prescription for NPEP after reporting a higher-risk exposure by phone but did not follow up in person, were prescribed antiretrovirals for anything other than NPEP, had occupational exposures, or were enrolled in an NPEP research trial. Visits for human bite wounds and insertive oral exposures were rare and excluded due to the low risk of HIV transmission associated with such exposures, and NPEP initiations more than 72 h after the exposure were excluded from the study due to presumed reduced efficacy of delayed NPEP initiation, as per the 2005 CDC guidelines.³

Extracted demographic information included: date of birth, date of initial encounter at the health center for any reason, date of last encounter with a medical provider at the health center for any reason with or without an HIV test, gender identity, race/ethnicity, gender preferences of sexual partner, any history of homelessness or unstable housing, education, and insurance status. HIV tests could have occurred without seeing a medical provider, and medical encounters did not always include an HIV test. "Visit" was defined as a single encounter with a medical provider on a given date. "Course" was defined as a series of visits that correspond to a single high-risk exposure for which NPEP was prescribed. Each patient could have had one or multiple NPEP courses over the study period. The following data were extracted at the time of presentation for each NPEP course: date of intake, reason for access, condom use, partner's reported HIV status, recreational substance use at the time of exposure, and transactional sex at time of exposure (either offering or receiving payment in exchange for sex). Prescribed antiretroviral regimen, regimen completion, reasons for documented non-completion or modifying the regimen, adverse effects, and follow-up at 1, 3, and 6 month intervals after the exposure were recorded. Any HIV test, including a rapid whole blood fingerstick assay or a serum antibody and/or plasma viral load, was required to count as having followed up a 3 and 6 months. The date of positive HIV serology was recorded for each seroconversion. All study procedures were approved by the Fenway Health Institutional Review Board.

Statistical methods

Proportions for categorical variables and means and standard deviations for continuous variables were calculated for

descriptive characteristics of the sample. A multivariable Cox proportional hazards model was used to assess factors associated with HIV infection, and backwards elimination with a cutoff of $p \leq 0.2$ was used to determine the final variables to retain in the model. Briefly, backwards elimination begins with all candidate variables in the model and removes them one by one, starting with the variable with the largest p value until all remaining variables in the model have a p value of ≤ 0.2 .^{14,15} Incidence of HIV was calculated per 100 person-years by dividing laboratory-confirmed incident cases by the total number of person-years at risk of follow-up in the study. The total number of person-years of follow-up at risk was considered to be time from first NPEP visit to last encounter with a medical provider or a later HIV test for individuals who did not seroconvert, and time from first NPEP visit to date of HIV seroconversion, respectively. Ninety-five percent confidence intervals for all incidence rates were calculated assuming a Poisson distribution.

Patient-level factors included age, race/ethnicity, insurance (any insurance versus none), enrollment in primary care at this community health center, depression diagnosis, anxiety diagnosis, chronic substance use disorder, and frequency of NPEP courses. All analyses were conducted in Stata version 12.1 (StataCorp, College Station, TX).

Results

Of 1084 unique medical records initially identified, 894 individuals who were prescribed 1244 courses of NPEP met the inclusion criteria. Reasons that data from 190 HIV-uninfected patients prescribed antiretrovirals were excluded were due to: no documentation of PEP or PrEP in the chart corresponding to date of antiretroviral prescription (21.1%), antiretrovirals prescribed for PrEP (21.6%) or chronic hepatitis B infection (11.1%), restricted access to electronic medical record (21.6%), occupational exposure (12.6%), patient called to request NPEP but did not follow up in clinic (3.2%), NPEP stopped at first visit because exposure deemed low risk by provider (2.6%), HIV diagnosed within 30 days of being on antiretrovirals for NPEP (2.1%), exposure was a human bite (1.6%) or insertive oral (0.5%), person was enrolled in an NPEP research study (1.1%), and presentation was more than 72 h post-exposure (1.1%). There were a total of 1751.8 person-years of follow-up among MSM in this study [median 1.11 years, interquartile range (IQR) 0.16–3.14 years]. Seventy-nine (10.0%) did not return for any follow-up after their initial NPEP visit. Among individuals who seroconverted, the median time from first NPEP visit until seroconversion was 1.53 years (IQR 0.85–3.07 years).

Of the 894 patients included in this study, 788 (88.1%) were MSM, 38 (4.3%) heterosexual men, 53 (5.9%) female, and 15 (1.7%) identified as transgender/genderqueer. Table 1 displays descriptive characteristics of MSM in the cohort. The following results pertain only to MSM. Of the 788 MSM in the study, the median age at first NPEP course was 32.9 years (IQR 26.9–40.8 years). The majority of patients (56.2%) had private insurance, 7.4% had Medicaid or other state-based health insurance or Medicare, and 36.5% were uninsured. Most patients were non-Hispanic white (588, 74.2%); 85 (10.8%) were Hispanic/Latino, 44 (5.6%) were African American/black, and 74 (9.4%) were Asian/Pacific Islander or identified as "other" for race or ethnicity. Fifteen

TABLE 1. DESCRIPTIVE CHARACTERISTICS OF MSM ACCESSING NPEP AT A LARGE COMMUNITY URBAN HEALTH CENTER, 1997–2013

Characteristic	Total	HIV seroconverted	No HIV seroconversion	p Value
Total number of participants	788	39	749	
Age at first NPEP course, years (mean, SD)	34.5 (9.5)	30.7 (7.5)	34.7 (9.5)	0.001
Race				
White	585 (74.4%)	29 (74.4%)	556 (74.2%)	0.051
Latino/Hispanic	85 (10.8%)	7 (18.0%)	78 (10.4%)	
African American/black	44 (5.6%)	3 (7.7%)	41 (5.5%)	
Other	74 (9.4%)	0	74 (9.9%)	
Insurance status				
No insurance	279 (35.4%)	15 (38.5%)	264 (35.3%)	0.93
Private insurance	463 (58.8%)	22 (56.4%)	441 (58.9%)	
Medicaid/Medicare/MassHealth	46 (5.84)	2 (5.1%)	44 (5.9%)	
In primary care at health center	514 (65.2%)	38 (97.4%)	476 (63.6%)	<0.001
Repeat NPEP course (> 1 NPEP course)	167 (21.2%)	12 (30.8%)	155 (20.7%)	0.16
STI at baseline	45 (5.7%)	4 (10.3%)	41 (5.5%)	0.27
Homelessness	15 (1.9%)	2 (5.1%)	13 (1.7%)	0.17
Total number of NPEP courses (range)	1,130 (1 to 15)	63 (1 to 7)	1,067 (1 to 15)	
Reason for NPEP presentation				
Unprotected consensual sex	726 (64.2%)	37 (58.7%)	689 (64.6%)	0.35
Condom failure/removal	351 (31.1%)	24 (38.1%)	327 (30.6%)	
Non-consensual sex/rape	34 (3.0%)	0	34 (3.2%)	
Injection drug use	7 (0.6%)	0	7 (0.7%)	
Partner HIV status				
Known HIV-infected—on treatment	151 (13.4%)	6 (9.5%)	145 (13.6%)	0.08
Known HIV-infected—not on treatment	46 (4.1%)	3 (4.8%)	43 (4.0%)	
Known HIV-infected—treatment unknown	205 (18.1%)	19 (30.2%)	186 (17.4%)	
Unknown	728 (64.4%)	35 (55.6%)	693 (65.0%)	
Any recreational substance use at time of exposure	270 (23.9%)	19 (30.2%)	251 (23.5%)	0.23

MSM, men who have sex with men; SD, standard deviation.

(1.9%) patients had a history of homelessness. Most (65.2%) accessed their primary care at the health center where the study was conducted. Of the 788 MSM, 21.2% presented for NPEP 2 or more times. The number of NPEP courses ranged from 1 to 15.

Consensual unprotected sex was the most common reason for which individuals presented for NPEP (726, 64.2%; Table 1). Among consensual unprotected sex exposures, 425 (58.5%) included receptive anal, 277 (38.2%) included insertive anal, and 157 (21.6%) included receptive oral intercourse. Condom failure or removal was the second-most common exposure (351, 31.1% of NPEP visits). Patients may have reported more than one type of exposure when they presented for NPEP. Approximately one-third of patients (35.6%) reported having an HIV-positive partner, and half (50.8%) of these did not know if their partner was on treatment or which treatments they were receiving. Thus, overall 13.4% of all exposures involved an HIV-positive partner who was known to be on treatment. Thirty-four (3.0%) exposures were nonconsensual, and 0.6% of MSM presented for NPEP because of injection drug exposure. Substance use at the time of exposure was documented in 270 (23.9%) of exposures among MSM, most commonly alcohol (171, 15.1%). Of the 788 MSM, 167 (21.2%) returned for more than one NPEP visit. MSM who returned for more than one NPEP visit were slightly older at their first NPEP visit (median age 34.8 years, IQR 27.3–41.8) than those who only sought NPEP once (median age 32.5 years, IQR 26.8–40.7).

More individuals who sought NPEP more than once were Caucasian (134, 80.2%) compared to those who only sought NPEP once (451, 72.6%, $p=0.03$), and were more likely to have insurance (125, 74.9% compared to 384, 61.8%, $p=0.002$). Repeat NPEP visits were not more likely to be sought for consensual unprotected sexual encounters (229, 67.0% versus 497, 63.1%, $p=0.22$) or substance use at the time of exposure (85, 24.9% compared to 185, 23.4%, $p=0.65$).

Thirty-nine participants had a documented HIV seroconversion, all of which occurred in MSM more than 90 days after initially presenting for NPEP. The number of NPEP courses ranged from 1 to 7 with a mean of 1.6 courses per patient among those who seroconverted. The MSM-specific HIV incidence rate was 2.2 cases per 100 person-years (95% CI:1.6–3.0). New HIV infection was associated with younger age (adjusted hazard ratio=0.94; 95% CI:0.90–0.98), being Latino (adjusted hazard ratio=2.44; 95% CI:1.02–5.84), and/or being African American (adjusted hazard ratio=3.43; 95% CI:1.02–11.48) in the multivariable analysis (Table 2). Repeat NPEP use was not associated with HIV infection (adjusted hazard ratio=0.67; 95% CI:0.33–1.35). Of those who seroconverted, 97.4% were enrolled in primary care at the health center, whereas only 63.6% of those who did not have a documented seroconversion had established primary care at the health center. Of the 39 seroconversions, 4 occurred within 180 days of presenting for NPEP, specifically at 91, 133, 160, and 168 days post-exposure. All of these

TABLE 2. FACTORS ASSOCIATED WITH HIV SEROCONVERSION AMONG MSM (COX PROPORTIONAL HAZARDS MODEL)

	<i>Hazards ratio</i>	<i>p Value</i>	<i>Adjusted hazards ratio</i>	<i>p Value</i>
Age (per year)	0.94 (0.90 to 0.98)	0.002	0.94 (0.90 to 0.98)	0.003
Race				
Latino/Hispanic	2.33 (1.01 to 5.36)	0.046	2.44 (1.02 to 5.84)	0.044
African American/black	3.74 (1.13 to 12.5)	0.03	3.43 (1.02 to 11.5)	0.046
Any insurance	0.58 (0.31 to 1.12)	0.11	–	–
Primary care	3.16 (0.43 to 23.2)	0.26	–	–
Depression	0.88 (0.45 to 1.72)	0.71	–	–
Anxiety	0.73 (0.36 to 1.47)	0.38	–	–
Chronic substance use disorder	1.42 (0.72 to 2.78)	0.31	1.88 (0.93 to 3.81)	0.081
Repeat PEP use	0.73 (0.37 to 1.44)	0.36	0.63 (0.32 to 1.26)	0.193

exposures involved consensual unprotected receptive anal intercourse, 1 of whom reported substance use at the time of the exposure. They all received three-drug regimens, 3 of whom had documented regimen completion, and the completion status was unknown for one NPEP user. None of the 4 patients had clinical or laboratory evidence of a sexually transmitted infection within 2 weeks of NPEP presentation. The partners of 2 of the exposed patients were reported to be HIV-infected with unknown treatment status, and 2 partners had unknown HIV status. There was no documentation in the medical record of a recurrent exposure or lack thereof for any of these cases, nor was adherence discussed in detail.

Discussion

While several studies have reported HIV outcome data for NPEP users,^{4,5,16–19} this study spans the longest NPEP observational period of more than a decade. Among the 788 MSM NPEP users in the current study, subsequent HIV incidence was 2.2 infections per 100 person-years. The sample included predominantly Caucasian MSM with private insurance who presented after having an unprotected consensual sexual exposure, suggesting that most should have had the ability to access and follow up in primary care. In addition, incident HIV infection was associated with younger age, being African American, and/or Latino race, which is consistent with surveillance data published by CDC that demonstrated that the majority of new infections among youth in 2009 occurred among African Americans and Latinos.²⁰

The vast majority (89.7%) of the seroconversions were documented at least 6 months after presenting for NPEP. The timing of these infections suggests that non-adherence to the initial NPEP regimen or NPEP failure were not the problem, but rather the MSM had one or more new high-risk exposures. Moreover, recurrent use of NPEP was not statistically significantly associated with incident HIV infection compared to MSM who only completed one course, which was also noted in another large study of NPEP.¹⁷ These findings suggest that there is a subset of MSM NPEP patients who should transition to PrEP and other prevention interventions upon completing their initial NPEP course since they are recurrently risky, but may not accurately assess their risks after each exposure since they later acquired HIV and had missed opportunities to access NPEP or PrEP. There were 4 patients who had documented seroconversions more than 30 and less than 180 days after completing their antiretroviral NPEP course, which could represent possible NPEP failures,

cases of which have been reported in the literature.^{21–24} However, these early infections could also have been due to a new high-risk exposure after being on NPEP. Genotypes for the four new HIV diagnoses between 3 and 6 months were not available to determine whether their NPEP failures were due to transmitted or acquired resistance, and/or NPEP non-adherence. The serostatus or the plasma HIV viral load of the source patient was based on a patient's self-report but typically not available. In any event, almost 90% of the post-NPEP infections detected in this study were most likely due to subsequent later risk-taking and not a failure of the initial NPEP regimen.

This analysis represents the largest study of NPEP use among MSM in the US. However, there are several limitations of this study, starting with the retrospective design. Of those who seroconverted, 97.4% were enrolled in primary care at the health center, whereas only 63.6% of those who did not have a documented seroconversion had established primary care at the health center. This could have resulted in selection bias among those who had close follow-up and perhaps more frequent high-risk testing. If HIV seroconversions occurred among those with limited follow-up due to lack of primary care, or if the date of last HIV test alone was used as the end of the follow-up period, then the HIV incidence reported here would represent an underestimate. Alternatively, if the minority of patients without primary care at this center did not have a subsequent HIV seroconversion, then the HIV incidence reported here would be overestimated. In abstracting data from electronic medical records, we observed that some of the demographic information was incomplete. Follow-up HIV testing after the 6-month NPEP period was highly variable, which led to imprecision in measuring HIV incidence. In addition, not all 35 patients who had a subsequent HIV seroconversion necessarily had a documented post-exposure 6-month follow-up HIV test, so it is possible that some of these seroconversions could have been NPEP failures. Information about recurrent high-risk exposures after NPEP and prior to the subsequent seroconversion was not consistently queried by the medical provider for every patient, thus making it challenging to decipher the etiology of the seroconversion as an NPEP failure versus a new high-risk exposure. Unfortunately, information about follow-up testing outside of the study facility could not be accessed. Patients who had an HIV seroconversion within 30 days of being on antiretrovirals were excluded to limit confounding from patients that may have been infected prior to the NPEP exposure given the variable timing of when seroconversion occurs.²⁵

Many NPEP users in this study demonstrated ongoing high-risk behavior, as manifested by recurrent NPEP use, a high HIV incidence, and an increase in unprotected sex over time. NPEP users, particularly younger, Latino, and African American MSM, may benefit from careful risk assessment, culturally-tailored HIV risk-reduction counseling, and offer of pre-exposure prophylaxis. The HPTN 061 study also noted a disproportionately high incidence of HIV among a large prospective cohort of African American MSM, which was even higher among MSM less than 30 years old.²⁶ Further analyses from this cohort demonstrated that newly diagnosed African American MSM were more likely to have sexually transmitted infections and reported more unprotected receptive anal intercourse in the previous 6 months compared to those who remained uninfected, factors which are likely to be fueling the HIV epidemic among young African American MSM.²⁷ Latino MSM are also experiencing disproportionately higher rates of HIV incidence as compared to non-Latinos,²⁹ which has been attributed to low utilization of condoms due to pleasure inhibition,^{28,29} lower self-efficacy, poorer communication skills, and concomitant substance use.²⁸ Higher rates of unprotected anal intercourse have also been reported among African American and Latino MSM with older male sex partners, which were independently associated with unrecognized HIV infection.³⁰ Given the increases in HIV prevalence and incidence in many regions around the world,³¹ studies to determine how to best educate at risk MSM and providers about NPEP, and the development of programs to seamlessly transition high risk NPEP users to PrEP are needed in order to arrest further spread in this population. Additional research is necessary to identify NPEP users that would be appropriate candidates for PrEP in other settings, as well as to guide implementation of PrEP with regard to timing of follow-up HIV testing, when to start PrEP, and behavioral counseling in NPEP-experienced patients.

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